REMARKS

Claims 1-38 are currently pending. Claims 11, 12, 18-22 and 29-36 are withdrawn. Claims 1, 3, 7, 14 and 25-27 are currently amended. Claim 37 and Claim 38 are new. Support for the amendments to the claims can be found at, for example, paragraphs [0057], [0058], [0076], [0078] and [0112], which teach a step using a first filter for eliminating blood cell aggregates having pore sizes between about 2 μm to about 20 μm or 11 μm and 5 μm specifically as well as a step for recovering contaminating microbes using a second filter having pore sizes between about 0.2 μm to about 2 μm step or 0.45 μm specifically.

The Examiner is thanked for granting an interview with the Applicant's representative on April 9, 2008. During the interview, it was established that neither Doshi, Schrenk or the other prior art of record taught methods steps involving recovering microbes on a second filter or analyzing material captured on a second filter to detect labeled microbes and that obviousness of the claims under 35 U.S.C. §103(a) could not be established based on the combination of these references. Also discussed during the interview was the importance of the second filter pore size and that recitation of a second filter pore size of "about 0.4 μm," should be allowable over current prior art of record. This response is believed to be consistent with the substance of the discussion during the interview granted by the Examiner.

Claims 1-5, 8, 10, 14-17 and 23-28 are rejected under 35 U.S.C. §103(a) as being obvious over the combination of Doshi and Schrenk. The rejection states that Doshi teaches contacting a blood sample with an agglutinating to aggregate blood cells, removing agglutinating cell clumps with a filter having pore sizes between 20 and 500 μm, and a second filter with pore sizes between 1 and 5 μm to permit plasma to pass through the second filter, and a reactant pad which produces a detectable signal in the filtered liquid that has passed through the second filter. The

rejection states that Doshi does not teach lysing residual blood cells in the filtrates. The rejection states that Schrenk teaches a reagent that selectively lyses blood cells, but not contaminating microbial cells, a single filter to remove plasma from the sample, and testing of the retentate in the first chamber upstream of this single filter for the presence of microbial contaminants.

Claims 1-5, 8, 10, 14-17 and 23-28 are not obvious under 35 U.S.C. §103(a) over the combination of Doshi and Schrenk. First, neither Doshi nor Schrenk teach "a second filter with a pore size of about 0.3 μm to less than 1 μm which retains contaminating microbes and allows passage of cellular debris[.]" This is significant because an appropriate balance needs to be struck between pore sizes which are so small that cellular debris is retained creating high background fluorescent signals, for example, that prevent the cellular debris and labeled microbes to be distinguished such that the labeled microbes are detectable above the background level, and a pore size which is sufficiently larger enough that cellular debris can pass through yet labeled microbes will be retained. Second, neither Doshi nor Schrenk teach "analyzing material on [a]...second filter to detect labeled contaminating microbes[.]" Doshi is silent concerning assays for microbial contaminants. Schrenk merely teaches that the blood cell containing fluid present as a retentate in the first chamber of the apparatus of Schrenk can be assayed for the presence of microbes. Stated differently, the assay of Schrenk does not involve analyzing material on the filter, but instead involves analyzing liquid material. Consequently, the rejection fails to establish that the combination of Doshi or Schrenk teaches all the elements of the methods of Claims 1-5, 8, 10, 14-17 and 23-28. The rejection thus fails to establish *prima facie* obviousness. The Applicants respectfully request withdrawal of the rejections of Claims 1-5, 8, 10, 14-17 and 23-28 as obvious under 35 U.S.C. §103(a) over Doshi and Schrenk.

Claim 6 and Claim 7 are rejected under 35 U.S.C. §103(a) as being obvious over the

combination of Doshi, Schrenk and Cathey. The rejection states that the teachings of Doshi and Schrenk are essentially as described above. The rejection states that neither Doshi nor Schrenk teaches a fluorescence based microbial cell marking system or agents.

Claim 6 and Claim 7 are not obvious under 35 U.S.C. §103(a) over the combination of Doshi, Schrenk and Cathey. As discussed above, Doshi and Schrenk fail to teach all the elements of the claims. In particular, Doshi and Schrenk fail to teach "a second filter with the pore size of about 0.3 μm to less than 1 μm which contains contaminating microbes," or "analyzing material on the second filter to detect labeled contaminating microbes[.]" The teachings of Cathey with regard to the use of a fluorescence based microbial cell marking system or agents do not correct the deficiencies of Doshi and Schrenk. Consequently, the rejection fails to establish that the combination of Doshi, Schrenk and Cathey teaches all the elements of the methods of Claim 6 and Claim 7. The rejection thus fails to establish *prima facie* obviousness. The Applicants respectfully request withdrawal of the rejections of Claim 6 and Claim 7 as obvious under 35 U.S.C. §103(a) over Doshi, Schrenk and Cathey.

Claim 9 and Claim 13 are rejected under 35 U.S.C. §103(a) as obvious over the combination of Doshi, Schrenk and Besson-Faure. The rejection states that the teachings of Doshi and Schrenk are essentially as described above. The rejection also states that Doshi and Schrenk do not teach an antibody specific to a platelet antigen such as anti-GpIIb/IIIa. The rejection states that Besson-Faure teaches the agglutination of blood cells with an anti-GpIIb/IIIa antibody.

Claim 9 and Claim 13 are not obvious under 35 U.S.C. §103(a) over the combination of Doshi, Schrenk and Besson-Faure. As discussed above, Doshi and Schrenk fail to teach all the elements of the claims. The teachings of Besson-Faure with regard to the agglutination of blood

cells with an anti-GpIIb/IIIa antibody do not correct the deficiencies of Doshi and Schrenk. Consequently, the rejection fails to establish that the combination of Doshi, Schrenk and Besson-Faure teaches all the elements of the methods of Claim 9 and Claim 13. The rejection thus fails to establish *prima facie* obviousness. The Applicants respectfully request withdrawal of the rejections of Claim 9 and Claim 13 as obvious under 35 U.S.C. §103(a) over Doshi, Schrenk and Besson-Faure.

In light of the foregoing, the Applicants respectfully submit that the entire Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,

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